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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/024,988	02/17/98	NELSON	R 5015C1

EXAMINER	
LINGAR, S	

ART UNIT	PAPER NUMBER
1642	12

HM22/0315

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DATE MAILED: 03/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/024,988	Applicant(s) Nelson et al
	Examiner Unger	Group Art Unit 1642

☒ Responsive to communication(s) filed on *Jul 27, 2000* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *31-47* is/are pending in the application.

Of the above, claim(s) *32, 34-39, and 42-47* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *31, 33, 40, and 41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. The Amendment filed July 27, 2000 (Paper No. 11) in response to the Office Action of May 22, 2000 (Paper No. 10) is acknowledged and has been entered. Claims 31, 33, 40 and 41 currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following objections are maintained:

4. The objection to the declaration and the requirement for a new declaration recited in Paper No. 10 is maintained for the reasons previously set forth in Paper No. 10, Section 3, page 2.

Applicant argues that Applicant knows of no statue or rule that requires a single declaration naming all of the applicants submitted with a patent application and the objected to declaration specifically states that Inventor Krone is a "co-inventor". The argument has been considered but has not been found persuasive as it appears that Applicant has not carefully read the objection. Examiner specifically pointed to the requirement that the declaration must comply with 37 CAR 1.67(a) which specifically states that a supplemental declaration must meet the requirements of 37 CAR 1.63 which specifically requires the identification of each inventor as well as their residence and country of citizenship. Further 37 CAR 1.64 specifically requires that the declaration must be made by all of the actual inventors, except for those that are dead, insane or legally incapacitated. Applicant's arguments have not been found persuasive and the objection is maintained.

5. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

6. Claims 40 and 41 remain rejected under 35 USC 112, second paragraph for the reasons previously set forth in Paper No. 10, Section 4, page 3.

Applicant argues that the claim a reasonable reading of the claim is "either each standard preparation contains a known amount of said IRS or each standard preparation contains an equal amount of said IRS". The argument has been considered but has not been found persuasive for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained. The rejection can be obviated by amending the claim to recite the reasonable reading suggested by Applicant.

7. Claims 31, 33, 40 and 41 remain rejected under 35 USC 112, second paragraph for the reasons previously set forth in Paper No. 10, Section 4, page 3.

Applicant argues that, as taught in the specification, the act of capturing the analyte (and IRS) accomplishes the act of isolating the analyte (and IRS). The affinity reagent captures the analyte (and IRS) and simultaneously isolates them from any contents remaining in the specimen, thus the IRS is captured, is isolated, as is stated in the claim. The argument has been considered but has not been found persuasive because it is not clear why Applicant has enclosed the "and IRS" in parenthesis, nor has Applicant pointed to page and line numbers in the specification for support of the argument. Is the limitation inferred, implied or specifically stated? Further, even if the limitation were specifically stated, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Guens , 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.

1993)". Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

8. Claims 31, 33, 40 and 41 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 10, Section 6, pages 4-7.

Applicant argues that (a) the '779 patent is not applicable to the present application because the portion of the '799 patent cited is really a method for determining whether a positive test result should be believed and that the cited method "comprises a confirmatory assay" and the method is not used in the quantitative determination of analytes in test samples, (b) nothing in the combined prior art provides a quantitative measure of an analyte as is claimed in the present invention.

The argument has been noted but has not been found persuasive because (a') Applicant is arguing limitations not recited in the claims as presently constituted. While a) is drawn to combining the IRS with the analyte, it is combined in order to calibrate all subsequent steps and only in c) is the quantifying step recited. It is reasonable to find, in the absence of a clear definition of "calibration" in the specification, that the step in the method of the '779 patent, "wherein the analyte is contacted with a predetermined amount of labeled reagent (the IRS)" corresponds to a) of the instant application, since the step establishes a positive control which calibrates the rest of the steps of the assay, (b') Van Ginkel et al clearly provides a quantitative measure of an analyte, the '779 patent was cited to provide motivation for providing the IRS in the first step of the Van Ginkel et al method. Given the

teaching that the method of the '779 establishes a positive control, the motivation provided is clear. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

9. All other objections and rejections recited in Paper No. 10 are withdrawn.

10. No claims allowed.

11 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
March 13, 2001